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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ADAMS, AMANDA S

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,372

Applicant(s)

BERUBE ET AL.

Examiner

Amanda Adams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,10-12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) 3-5,8,9,13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,10-12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/8/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: There are a few instances of improper grammar, such as in paragraphs 0006 lines 6-7, paragraph 0025 line 9, paragraph 0026 line 6, and paragraph 0027 line 9.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10 recites the limitation "the inner surface" in line 3 of the claim. Claim 1 recites "the surface" but not an inner surface. There is insufficient antecedent basis for this limitation in the claim.

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "about" does not clearly define the temperature range that is claimed by the applicant.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

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Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 2, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al (US 6,527,767).

4. Wang et al disclose the invention substantially as claimed including a first jaw member with a recess in the surface thereof to receive an ablation device (fig. 11A [78] is a recess in the inner surface of that jaw member; [68] is ablation device), a second jaw member opposed to the surface of the first jaw member (fig. 9 [60] are the arms or jaw members), and a structure attaching the jaw members to each other for selectively effecting closure to the jaw members to operatively engage the ablation device upon a target tissue disposed between the jaw members (fig. 14A), wherein the first jaw member includes at least one cross member for retaining the ablation device in the recess (fig. 15, the structural components between the ablation electrodes are considered to be the cross members), and wherein the jaw members extend in an elongated direction and are hinged together for relative rotation between open and closed configurations along an axis substantially aligned along the elongated direction (fig. 3).

5. Regarding claim 15, Wang et al disclose that one of the jaw members can be flexible and contain a retaining element that is capable of retaining a manually bendable configuration (col. 5, lines 45-50).

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6. Regarding claim 16, Wang et al disclose a retaining element (the ablation electrodes and components) that prevent the jaw member from being manually bent in a direction orthogonal to that direction in which it can be bent due to the jaw materials flexible properties (col. 5, lines 45-50; the ablation components can't be bent even though the jaw can).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, 7, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (US 6,527,767) in view of Hooven et al (US 6,517,536).

9. Regarding claims 6 and 7, Wang et al disclose the invention substantially as claimed above including a transmural system but fail to disclose a transmural system where the completion of an ablation lesion in the target tissue can be monitored by at least two electrodes that transfer a signal between each other through the target tissue. However, Hooven et al teach a transmural ablation device wherein the electrode disposed on the jaw members transfer electrical signals therebetween through the target tissue to measure the impedance through the target tissue and determine when an ablation lesion had been formed therein (col. 8, lines 48-67). This provides a critical feedback system for the surgeon, so that he or she does not ablate more tissue than is

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necessary and so that the device does not have to be continually removed to monitor the ablation progress. Therefore it would have been obvious to have a transmural device with an ablation monitoring system.

10. Regarding claim 18, Wang et al disclose the invention substantially as claimed above but fail to disclose jaws that open laterally with respect to a hinge axis as the mechanism for alternating between open and closed configurations. However, Hooven et al teach a pair of jaws on a similar device wherein the jaws open by translating laterally along the hinge axis (compare figs. 36 and 37). This provides another way to open and close the jaws that reduces the chance of bumping into tissue that was not meant to be operated on. Therefore it would have been obvious to open and close the jaws of the transmural ablation device in such a way as that of Hooven et al.

11. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (US 6,527,767) in view of Francischelli et al (US 6,584,360).

12. Wang et al disclose the invention substantially as claimed above except for failing to disclose the following which is taught by Francischelli et al. Francischelli et al teach that it is old and well-known in the art to use a liquid crystal display to provide a color change in response to ablation temperature in the target tissue (col. 7 lines 60-65), wherein the liquid crystal sheet is adapted to change color at a temperature in the range of 48 C to about 52 C (col. 7, lines 50-60), and wherein the liquid crystal sheet provides a color gradient corresponding in response to a temperature gradient monitored in the target tissue (col. 7, lines 47-59). It would have been obvious to place the liquid crystal sheet on the inner surface of one of the jaw members because that is the closest the

sheet can get to the ablated tissue, and it also reduces the number of instruments that must be used by the surgeon, thus shortening the total time for the procedure. Having a temperature feedback system helps to ensure that the surgeon does not ablate more tissue than is necessary and also prevents the device from having to be continuously removed to monitor the ablation progress. Therefore it would have been obvious to have such a liquid crystal sheet on the inner surface of one of the jaw members.

Response to Arguments

13. Applicant's arguments filed August 8, 2006, have been fully considered but they are not persuasive.

14. Regarding claim 1, Wang et al does show that the ablator is on a surface of the jaw member. The limitations of claim 1 do not specify what surface the recess must be on. Therefore any prior art in which a recess for the ablator exists on any surface of the jaw member can be used to reject the limitation. In the case of Wang et al, the recess is within the surface of the inner lumen of the jaw member.

15. Regarding claim 7, the limitations of the claim do not specify that the electrodes are separate from the ablation device.

16. Regarding claims 10-12, it would have been obvious to place the liquid crystal sheet of Francischelli et al on the inner surface of one of the jaw members as explained above.

17. The cancellation of claims 3-5, 8, 9, 13, and 14 is acknowledged.

Conclusion

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18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 10/11/06


GLENN K. DAWSON
PRIMARY EXAMINER